

Evaluation Of Effect Of Argwadha Kwatha Nitya Virechana And Nishakathkadi Kwatha In Madhumeha (Diabetes Mellitus II)

Dr. Shilpa B. Deshpande¹, Shweta Parwe², Manoj Patil³, Amoli Belsare⁴

¹PhD Scholar, Mahatma Gandhi Ayurved College, Datta Meghe Institute of Medical Sciences, Sawangi, Wardha.

²Assistant Prof., HOD, Department of Panchkarma, Vidarbha Ayurved College, Amravati.

³Research Consultant, Jawaharlal Nehru Medical college, Datta Meghe Institute of Medical Sciences, Sawangi, Wardha.

⁴Professor, Electronics & Tele. Engineering, Yeshwantrao Chavan College of Engineering, Nagpur

Email- ²sbdeshpande107@gail.com,

Abstract

Background - The diabetes is a carbohydrate metabolic disorder which is caused either due to the inadequate production or usage of insulin. In the modern world, the diabetes is often attributed to the changes in life style or life style related disorder. According to 'Ayurveda' the diabetes mellitus-II (DM-II) can be compared with Madhumeha. The symptoms of madhumeha which are highly similar to diabetes such as, frequent urination, excessive thirst, hunger, constipation, etc. For diabetes many treatment options are available amongst which, the Ayurveda can be one of the most promising alternative therapy. In Ayurveda, the Panchkarma, which is a purification process for the removal of toxins. In the Panchkarma, the virechana(laxative) is one of the five process involved in flushing out the toxins from the body. In the present study, Argwadha kwatha (decoction)obtained from the plant Cassia fistulais selected as a laxative for the effective treatment of madhumeha, owing to its multiple beneficiary effects.

Methodology- It is an open label, Randomized comparative clinical trial. Patients with high BSL level than normal will be enrolled with two groups each containing 75 patients. Intervention group trial with Argwadha kwatha Nitya Virechan 60 ml in the morning, And the second group trial with the Nishakathkadi kwatha 20 ml B.D.for 21 days with the 3 follow up. Assessment of result will depend on the BSL level and associated symptoms.

Expected Results- the final outcome will show the lowering of BSL level in the patient of Madhumeha. It is the evidence-based trial for the virechana procedure and relief the symptoms in the patient of madhumeha.

Keywords- Nitya virechana, Madhumeha, Argwadha, Nisha kathkadi kwath. Diabetes melitus II.

1. INTRODUCTION:

Diabetes mellitus is defined as a disturbance in carbohydrate metabolism, exhibiting as a chronic sustained hyperglycaemia primarily due to reduced insulin production or decreased

insulin sensitivity¹. In the world wide population, 415 million people are affected by diabetes, amongst which a significant cases are form India, which are ever increasing at rapid rate. With this high rate, India is already a 'Diabetes capital' of world, with over 30 million of affected patients^{2,3}. The severity of the diabetes is very high and it is predicted that at every 6 seconds one person dies from diabetes or associated complications. This estimated is to rise for 642 million by 2040². Diabetes Mellitus (DM II) has a strong genetic susceptibility to the endocrine system and insulin regulating tissue. Diabetes is characterized by several environmental factors which is associated with impaired beta cell functions and insulin resistance⁴. *Madhumeha*, is concord with Non-Insulin Dependent Diabetes Mellitus (NIDDM II) is one amongst the *Vataja Prameha* that has been considered as *Mahagada*^{5,6}. In Ayurveda, Charakaa has classified *Madhumeha* a one of 20 *Prameha* (urinary disorders). As the *Madhumeha* is *vata* influenced, *Kapha* disease it can be better managed with Nitya virechana [laxative].

Background

Madhumeha

It is the disease which is the *kledpradhan vyadhi* associated with symptoms like frequent urination. It is the one of the type of *Prameha*. The major causes of the disease mainly but not limited to excessive use of dairy products, sugar products, *navdhanya*, rice, sea food, excess sleep, lack of exercise. Tridosha responsible for disease as *prameha* which is characterized by *dhushya* such as *Med*, *rakta*, *vasa*, *lasika*, *mansa*, *rasa*, *oja*, *kleda*, *majja*, *shukra*.

Symptoms of *prameha* includes, excessive thirst, *prabhutavilmutra*, *hast pad taladaha*, *gurugatrata*, *swedadhikya*, *atinidra*, *kshudhadhikya*, *daurbalya*⁷. Elevated *ama* (undigested food) combined with the *tridosha*, and *meda*, moving towards *mutravaha srotas* (urinary system) in lower part of body and accumulate in the bladder⁸. For the effective treatment of *Madhumeha*, *Shodhan chikitsa* (treatment) for the *sthul-pramehi* (obese) and for *krusha* (lean) person has been practiced along with *santarpanchikitsa*⁹.

Virechana

Virechana is the process in which the dosha is removed from the *adhomarg* that is the anus. It is the major treatment of the *pitta* and the *kapha*. *Virechana* drug is mainly of *pruthvi* and *jalmahabhut pradhan*. The *doshas* (toxins) goes down and wash out by anus¹⁰. *Virechansadhya* disease the *gulma*, *arsha*, *kamala*, *vyanga*, *jirnajwara*, *udar*, *halimak*, *vidradhivatrakta*, *krumikoshtha*, *mutraghat*, *adhograktpitta*, *kushtha*, *meha*¹¹. *Samyak virechana lakshan* *kaphadi dosha* wash out from the body and results in lightness in the umbilical region, calmness of mind, *vatanulomana* is seen¹². Generally *virechana* should be done in *sharadrutu* (autumn). *Virechana* process can lead to significant reduction in blood sugar level¹³.

Nitya virechana is the term correlated with the *mrudu anuloman* (laxative). In *Madhumeha* toxins that are accumulated in bladder which leads to frequent urination. It is reported that the Nitya virechana can results in removal of *Dosha* (toxins) which are associated with *Madhumeha*.

Argwadha

Argwadha is the *dravya* reported as *virechakdravya* in *Charaksamhita*. *Argwadha* removes the *doshas* (toxins) which stick on the walls of *koshtha* (digestive track). It is characteristically, *pathyadravyamrudu*, *madhur and shital*, used in the children as well as old age patients as it does not lead to any complications and considered as harmless¹⁴. In *Chakradatta*, the *chaturangulakwatha* is reported for the treatment of *prameha*¹⁵. In *Bhavpraksh*, the *argwadha*

is reported for the treatment of *jwar* and it is also known as *askoshth-shuddhikar param*. In *prameha-dosha* in the lower part of body so the argwadha used as the *adhobhaghar-dravya*¹⁶.

Nishakathkadi kwatha

Nishakathkadikwath is well known hypoglycemic drug reported in the *Sahasrayoga*. This *kwatha* include *nisha, kathak, paranti, jodhra, amalki, bhadraka, meshshrungi ushira*. All the components of this *kwatha* are *pramehhar*¹⁷

Rationale

With ever increase in prevalence of the diabetes mellitus, its efficient treatment and management has become the need of the hour across the globe. Globally has become a life-threatening problem. Ayurveda a standard and traditional medicinal system has contributed many therapeutic options to combat this life style disorder. Economic and effective management for the pre diabetic and diabetic affected individuals is proposed here with the examples from the past literature.

Research gap analysis

Madhumeha is the *bahudosh* vyadhi as explained in Ayurveda. One of the effective method of treatment or management of the *Madhumeha* can be *shodhana* [purification]^[18-19]. However, the '*Shodhan*' process as is not studied in detail for the management of diabetes mellitus. Especially, the use of *Nitya Virechan* (laxative) with the *Argwadha kwatha* is not studied. *Based on the gap in literature and previous studies, here a study is proposed to assess the effect of Argwadha kwath for nitya virechana for the effective management of diabetes mellitus (madhumeha)*

Objectives

- To study the effect of *Argwadha kwatha nitya Virechana* in lowering the blood sugar level
- To study the effect of *Nishakathkadi kwath* (oral) in lowering the blood sugar level.
- To compare the effect of *Argwadha kwath virechana* and *nishakthkadi kwatha* in lowering the blood sugar level.

In *Madhumeha*, previous studies showed the reduction of blood sugar level using several drugs, however, the *Panchakarma* procedure which can lower the blood sugar levels are not studied yet. *Shodhan* procedures are often suggested but the action of the *shodhan* (*Virechana*) is not studied. Beside of this, *Argwadha Nitya virechan* in *Madhumeha* is not yet studied. Especially *Nitya Virechan* [laxative] with the *Argwadha kwatha* is not studied as treatment in *Madhumeha*. Neither a comparative study is recorded with *Nishakathkadi kwatha*.

Need establishment: There is a need to understand the *Argwadha kwath nitya virechan* action on the blood sugar levels in *Madhumeha* as a therapeutic and prophylactic.

Trial Design- It is the open labelled, parallel, noninferiority, Random comparative clinical trial.

2. METHODOLOGY

The data will be collected from the undertaken at OPD and IPD of Mahatma Gandhi Ayurved College Hospital and research Centre, Salod (H) Wardha. Maharashtra. India.

Inclusion criteria

- Age above 20 years and below 60 years
- Patients newly diagnosed with diabetes

- Patients fit for *Virechana*.
- Exclusive criteria
- Patients below 20 years and above 60 years,
- Pregnancy, childbirth and puerperium period (ICD-10 criteria 024),
- Glycosuria NOS(ICD -10 criteria R81) or renal(ICD-10 criteria E74.8),
- Impaired glucose tolerance(ICD -10 criteria R73.0)
- Patients of DM-Type1
- Type-2 Diabetes patients on insulin therapy.
- DM with Retinopathy, Nephropathy & previous H/O Coma.

Intervention- Interventional group is the Argwadha Kwatha for Virechana(Group A) and Nishakathkadi kwatha as a comparator group (Group B).

In each group 75 patients will be enrolled and study will be conducted on total of 150 patients including the Group A and Group B

Group A Argwadha kwatha:

The Argwadha kwatha is prepared with the 3 gm of fal majja(fruit pulp) of Argwadha legumes and the kwatha (decoction) about 60 ml will be prepared as one part of drug and 16 parts of water boiled and reduced to eight part.

Kwatha dose for virechana will be given to patient at each morning between 9 am to 10 am. The amount of dose of kwatha will be increased until the virechana effect is observed in patients. Dose will be given for a total of 21 days. Follow-up at after every 7 days. After that the virechan lakshan will be studied.

The table below describes the details of the Argwadha to be used in the trial.

Sanskrit name	Botanical name	Plant part to be used	Quantity
<i>Aragwadha</i>	<i>Cassia fistula</i>	<i>Fal majja</i>	3gms

Table-1

Group B Nishakathkadi kwatha:

This is a comparator group. As described earlier, the Nishakathkadi kwatha is known for its antidiabetic properties will be used as positive control. The similar procedure for the preparation used in the preparation of Argwadha kwatha will be followed for the preparation of Nishakathkadi kwath . It will be given as B. D form after the meal. The dose of kwatha is about 20mL two times. Dose will be given for a total of 21 days. Follow-up at after every 7 days.

The Table below describes the details of Nishakathkadi kwath

Sanskrit name	Botanical name	Used part	Quantity
<i>Nisha</i>	<i>Curcuma longa</i>	Roots	33 mg
<i>Kathka</i>	<i>Strychous potatatorun</i>	Seed	33 mg
<i>Paranti</i>	<i>Ixoria coccinia</i>	Leaves, roots	33 mg
<i>Lodhra</i>	<i>Symplocos recemosa</i>	Bark	33 mg
<i>Amalaki</i>	<i>Embllica officinalis</i>	Fruit	33 mg
<i>Bhadrika</i>	<i>Aerva lanata</i>	Fruit, roots, stem,	33 mg
<i>Meshshrungi</i>	<i>Gymnema sylvestre</i>	Root	33 mg
<i>Usheera</i>	<i>Vetiveria zizanioids</i>	Root	33 mg

Table-2

If the patients found to have hypoglycaemia or similar symptoms the trail should be discontinued.

The criteria for assessment will be –

- Blood sugar level fasting and post meal
- Ccompleteblood Cell count (CBC)
- Erythrocyte sedimentation rate
- Lipid profile
- Urine routine and microscopic examination
 - Specific investigation- HbA1c Clinical parameters –
- *Prabhutmutrata*(frequencyofurine)
- *Sramaswasa*(Dyspnoea)
- *Mukhamadhurya*(Sweetness in mouth)
- *NaktaMutrata*(nocturnal micturition)
- *Vibandha*(Constipation)
- *Pipasa*(Increased Thirst)
- *Daurbalya*(weakness)
- *Swedaadhikyata*(Perspiration)
- *PipilikaSancharat*(Tingling sensation)
- *Kshudhadhikya*(Increased Appetite)
- *HastaPadaTalaDaha*(burning sesetion of hand and feet)
- *Atinidra*(Increased Sleep)
- Investigative parameter
- *Avil mutrata*(*Turbidity*- newspaper test)
- Haematological- CBC ESR, BSL- fasting and post meal. Lipid profile.
- Urine-urine routine and microscopic.

Gantt chart for the study timelines

Timelines	Q1	Q2	Q3	Q4	Q5	Q6
Enrolment of Patients						
Medicine preparation						
Data collection						
Writing thesis parts up to Methods						
Data analysis						
Writing rest of thesis						
Submission						

**Table-3
Sample size**

Patient willingness, patient who are fit in the inclusive criteria and the symptoms of madhumeha (frequent urination, polydipsia, weakness) and the raised BSL level.

Population Size: 200,000; Confidence Level (%): 95% Margin of Error(%):10%

Sample size: **150** by using normal distribution (50%)75for each group (trial and control) By

using

formula:

$$\text{Sample Size} = \frac{\frac{z^2 \times p(1-p)}{e^2}}{1 + \left(\frac{z^2 \times p(1-p)}{e^2 N}\right)}$$

Population Size = N | Margin of error = e | z-score = z is percentage, put into decimal form (for example, 3% = 0.03)

Allocation

The data sampling will be done by lottery method with the numbering chits. The data will be collected from the patient who visits to the OPD on the basis of symptoms and the BSL testing. The patient will be enrolled by chit method. Numbering of the chits with the group A/B. the consent form will filled up and will be recorded on the computer. The sample enrolled will be in close envelop of each group. Each 75 patients will be enrolled in each group. The patient should take the treatment for 21 days with the follow up on each 7th day. After 21 days the patient will be observed for 7 days. The patient who discontinue or taking another treatment for the same, or showing any adverse effect will be dropped out from the study. The patient will be given a hard copy file to keep the record, and the record will also be maintain the staff who will keep the data securely and properly. All the data shall be kept in Panchkarma department.

Statistical Method

Unpaired t test will be applied on the clinical and investigative parameters before and after the study of same group. and paired t test will be applied on both the groups for compare the clinical and investigative parameters of the study.

Outcome:

Primary outcome will be the lowered BSL level. The sugar level within normal range with the decreased symptoms such as *Prabhutmutrata* and *Naktmutrata*

Secondary outcome will be decreased symptoms from severe to moderate, moderate to mild and mild to normal. *Sramaswasa*(Dyspnoea), *Mukhamadhurya* (sweetness in mouth), *Vibandha* (Constipation), *Pipasa* (increased thirst), *Daurbalya* (weakness), *Swedaadhikyata* (Perspiration), *PipilikaSancharat*(Tingling sensation), *Kshudhadhikya* (increased appetite), *Hasta Pada Tala Daha* (burning sensation of hand and feet) *Atinidra etc.*

Tertiary outcome- HbA1C will be within normal level, other blood investigation parameters should be within normal level.

Data monitoring: Ph.D. guide will review the work of the student; the institutional PhD committee will review the work within time period. The periodically reporting will be at each 6-month interval.

Ethical committee will see any adverse events and other unintended effect of the trial will be guided to discontinue the trial if any adverse events arises.

Ethical committee: Institutional ethical committee of MGAC and H Wardha. Second approval for this study is from doctoral research committee which is WHO recommended committee of DMIMS university, Nagpur. The CTRI registration no is-REF/2019/10/028633.

Every enrolled patient will be given a consent form in Marathi, Hindi, English. Any time the

patient rejects for the study or withdraw. Separate file should provide to the patient for maintaining the record of patient .and the study on the patient record in the computer with password protection. Any personal information of patient will remain confidential. And proper precaution shall be given for the same.

The publication on this study will on the basis of review topic and after completion of study. For public information the publication will show the results of study and efficacy.

Expected Outcomes/Results:

- Blood sugar level will be reduced to normal level with the treatment of the Argwadha kwatha
- Madhumeha associated symptoms such as *Prabhutmutrata* , *Naktmutrata* and other symptoms are expected to be decreased from severe □ mild □ normal
- Decreased triglyceride and HbA1c levels

3. DISCUSSION:

In the Diabetes patient the dosha are accumulated in the lower body so nearest route for removing the doshyas is the Virechana^{18,19}. Argwdha kwatha is the Virechana drug which will be given in the form of Nitya Virechana. Therefore, the effect of Nitya virechana would be on lowering of blood sugar level. In the patient of Madhumeha there is constipation symptoms so by the virechana process it will relieved. The study intended for reducing the blood sugar level of the madhumeha patients using Virechana as one of the Panchkarm process will be established. The efficacy of proposed Argwadha drug will be compared to Nishakathkadi kawtha (already used in Madhumeha treatment) and suitability of the same for reduction of madhumeha related symptoms and improved blood sugar metabolism will be established. Related articles on diabetes from this region are available. Rathi et al reported nerve conduction studies of peripheral motor and sensory nerves in the subjects with prediabetes²⁰. Ray et al studied effects of alirocumab on cardiovascular and metabolic outcomes after acute coronary syndrome in patients with or without diabetes²¹. Khatib et al suggested M-HEALTH intervention for type ii diabetes mellitus patients in Indian rural areas²². Shrivastava et al conducted assessment of Mean Platelet Volume (MPV) in subjects with Type 2 Diabetes Mellitus²³. Gaidhane et al reviewed perceptions of primary care doctors towards type 2 diabetes mellitus and challenges for care at primary care level in India²⁴. Gondivkar et al conducted evaluation of gustatory function in patients with diabetes mellitus Type 2²⁵. Shinde et al reported on Prameha and Diabetes Mellitus²⁶. Wagh et al studied the role of Vitamin-c Supplementation in Type II Diabetes Mellitus²⁷. Studies related to effects of diabetes on kidney²⁸ were reported. Articles from global burden of disease study are available^{29,30}.

REFERENCES:

- [1] Davidson's principle and practice of medicine, 19th ed. pp664
- [2] International diabetes federation ,IDF diabetes Atlas, 7th ed. Belgium IDF 2015.
- [3] API textbook of medicine chapter 18. shah SN editor, 7th ed. India, association of physicians
- [4] Davidson's principle and practice of medicine, 19th ed. pp664
- [5] International diabetes federation ,IDF diabetes Atlas, 7th ed. Belgium IDF 2015.
- [6] API textbook of medicine chapter 18. shah SN editor, 7th ed. India, association of physicians of India, 2003
- [7] Anthony S. Fauci et. Al. Harrison's principle of international medicine, Mc graw-hill 17th

- ed,2008 pg no.2275.
- [8] Yadavji Trikamji ed.Charak samhita of agnivesha (sanskrit) 5th ed. Prameha chikitsa 6/10,pg no.446
- [9] Yadavji Trikamji ed.Charak samhita of agnivesha (sanskrit) 5th ed. Prameha chikitsa 6/13,pg no.446 .
- [10] Brahmanandtripathi,charaksamhita-vol2, chaukhambaprkashan 2006,chikitsasthan6/4 page 279.
- [11] Sushrut samhita vol 1, Dr.Anant Ram Sharma chaukhamba prakashan 2015, Nidansthan 6/4 pg.502.
- [12] Brahmanand tripathi, charak samhita-vol 2, chaukhamba prakashan 2006,chikitsasthan6/15 page 286.
- [13] Brahmanand tripathi,charak samhita-vol2, chaukhamba prakashan 2006, kalpasthan1/4 page 1072.
- [14] Ashtang hruday Atridev vidyalankar chaukhamba prakashan ,sutr asthan18/8 page 75
- [15] Sushrutsamhita vol 2, Dr.Anant Ram Sharma chaukhambaprkashan 2015, chikitsasthan 33/24 pg.428.
- [16] Jindal N, Joshi NP. Comparative study of Vamana and Virechanakarma in controlling blood sugar levels in diabetes mellitus. Ayu. 2013 Jul;34(3):263.
- [17] Chakrdattachakrpanivirchit, Lakshmi vyanktesh press, 3rd ed. prameharogadhikar 9 pg.170
- [18] Brahmanandtripathi,charaksamhita-vol 2, chaukhambaprkashan 2006,kalpsasthan8/4 page 1118.
- [19] Dravygunavigyan vol2,priyavatsharma,chaukhamba prakashana,1990.pg no.170.
- [20] Manu KN. Clinical study to evaluate the therapeutic effect of nisha katakadi kashaya in madhumeha (Doctoral dissertation, RGUHS).
- [21] Rathi N, Taksande B, Kumar S. Nerve Conduction Studies of Peripheral Motor and Sensory Nerves in the Subjects With Prediabetes. Journal of Endocrinology and Metabolism. 2019 Oct 12;9(5):147-50. <https://doi.org/10.14740/jem602>.
- [22] Ray KK, Colhoun HM, Szarek M, Baccara-Dinet M, Bhatt DL, Bittner VA, Budaj AJ, Diaz R, Goodman SG, Hanotin C, Harrington RA. Effects of alirocumab on cardiovascular and metabolic outcomes after acute coronary syndrome in patients with or without diabetes: a prespecified analysis of the ODYSSEY OUTCOMES randomised controlled trial. The Lancet Diabetes & Endocrinology. 2019 Aug 1;7(8):618-28. [https://doi.org/10.1016/S2213-8587\(19\)30158-5](https://doi.org/10.1016/S2213-8587(19)30158-5).
- [23] Khatib N, Gaidhane S, Gaidhane A, Quazi Z. M-Health Intervention For Type Ii Diabetes Mellitus Patients In Indian Rural Areas. Indiabetes Technology & Therapeutics 2014 Feb 1 (Vol. 16, Pp. A95-A96). 140 Huguenot Street, 3rd Fl, New Rochelle, Ny 10801 Usa: Mary Ann Liebert, Inc.
- [24] Shrivastava P, Khatib MN, Gaidhane S, Shrivastava D, Gaidhane AM, Zahiruddin QS. Assessment of mean platelet volume (MPV) in subjects with Type 2 Diabetes Mellitus (T2DM) in a rural backdrop of central India. Medical Science. 2020;24(101):12-21.
- [25] Gaidhane S, Khatib N, Zahiruddin QS, Gaidhane A, Kukade S, Zodpey S. Perceptions of primary care doctors towards Type 2 Diabetes Mellitus and challenges for care at primary care level in India. International Journal of Diabetes in Developing Countries. 2015 Mar 1;35(1):14-8. <https://doi.org/10.1007/s13410-014-0199-6>.
- [26] Gondivkar SM, Indurkar A, Degwekar S, Bhowate R. Evaluation of gustatory function in patients with diabetes mellitus type 2. Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology. 2009 Dec 1;108(6):876-80. <https://doi.org/10.1016/j.tripleo.2009.08.015>.
- [27] Shinde RV, Rana AP, Rajurkar H, Kaple MN. Prameha and Diabetes Mellitus. Int J Cur

- Res Rev| Vol. 2020 Jul;12(14). <https://doi.org/10.31782/IJCRR.2020.9698>.
- [28] Wagh SP, Bhagat SP, Bankar N, Jain K. Role of Vitamin-C Supplementation in Type II Diabetes Mellitus. *Int J Cur Res Rev|* Vol. 2020 Jul 6;12(13):61. <https://doi.org/10.31782/IJCRR.2020.121311>.
- [29] Warjekar P, Jain P, Kute P, Anjankar A, Ghangale SS. Study of Microalbuminuria and Uric Acid in Type 2 Diabetes Mellitus. *Int J Cur Res Rev|* Vol. 2020 Jul;12(14). <https://doi.org/10.31782/IJCRR.2020.5665>.
- [30] Murray CJL, Aravkin AY, Zheng P, Abbafati C, Abbas KM, Abbasi-Kangevari M, et al. Global burden of 87 risk factors in 204 countries and territories, 1990–2019: a systematic analysis for the Global Burden of Disease Study 2019. *The Lancet*. 2020 Oct;396(10258):1223–49.
- [31] Vos T, Lim SS, Abbafati C, Abbas KM, Abbasi M, Abbasifard M, et al. Global burden of 369 diseases and injuries in 204 countries and territories, 1990–2019: a systematic analysis for the Global Burden of Disease Study 2019. *The Lancet*. 2020 Oct;396(10258):1204–22.